DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

P1130B

BUFFALO DISTRICT
Food and Drug Administration
599 Delaware Avenue
Buffalo, NY 14202

27 January 1997

WARNING LETTER BUF 97-9

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert D. Rothvoss, Sr., Co-Owner
Rothdale Farm
210 Rothvoss Lane
Ancramdale, NY 12503

Dear Mr. Rothvoss:

A tissue residue report from the United States Department of Agriculture (USDA), an inspection of your dairy farm, and related investigations by Food and Drug Administration (FDA) Investigator Perry T. Nichols, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act), as follows:

> On 16 September 1996, you consigned a cow, identified by sale tag #A617, permanent ear tag #21VAT0524, and USDA Domestic Laboratory Report #308622, for slaughter for human food. USDA analysis of tissues collected from the cow disclosed the presence of the drug streptomycin at a level of 12.0 ppm in the kidney.

The presence of this drug in edible tissues from cattle causes the food to become adulterated. A food is adulterated within the meaning of Section 402(a)(2)(D) of the Act if it contains a new animal drug which is unsafe within the meaning of Section 512 of the Act.

A food is also considered adulterated within the meaning of Section 402(a)(4) of the Act if it has been held under conditions whereby it may have been rendered injurious to health. Our investigation found you handled cattle under conditions which are inadequate to prevent medicated cattle bearing potentially harmful drug residues from entering the food supply. For example, you fail to maintain treatment records that include, among others, the identity of each treated animal, the date of the treatment, the drug(s) administered, dosage, route of administration, withdrawal times, and who administered the drug(s).

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action, such as seizure and/or injunction without further notice.

These violations are not intended to be an all-inclusive list. It is your responsibility to assure your operations are in compliance with the law. As a grower, you should take additional precautions to prevent future illegal residue violations, such as:

1) Assuring drugs are used in a manner not contrary to the directions contained in the labeling; and,

2) Implementing a system to assure animals medicated by you are withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues.

You should be aware, it is not necessary for you to have personally shipped an animal into interstate commerce to be responsible for a violation of the Act. The fact you offered an animal for sale through an auction who ships cattle to an interstate slaughterhouse, is sufficient to hold you responsible for a violation of the Act.

You should notify this office, in writing, within 15 days of the specific steps you have taken, or intend to take, to correct these violations. Your response may be directed to William J. Thompson, Team Leader, at the above address.

Sincerely,

E. Thompson for
Robert L. Hart
Acting District Director

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